K021696

510(k) Summary
As Required by 21 section 807.92 (c)

AUG 2 0 2002

1-Submitter Name: OphthalMed LLC
2-Address: 1308 Morningside Park Dr
Alpharetta, GA 30022 USA
3-Phone: (678) 908- 8180
4-Fax: (425) 795- 9341
5-Contact Person: Jay Mansour
6-Date summary prepared: April 8th, 2002
7-Device Trade or Proprietary Name: 20g and 25g SMA Laser Fibers
8-Device Common or usual name: Ophthalmic laser
9-Device Classification Name: Ophthalmic laser
10-Substantial Equivalency is claimed against the following device:
LightLas 532 Ophthalmic Photocoagulator Laser from Light med Corporation (510k #K010372)
Refer to Appendix 1 for details.

11-Description of the Device:

This device consists of the following parts already connected to each other:
- Handpiece with either a 20G or a 25G extension that holds the tip of the fiber and guides it inside the eye.
- 6 ft fiber.
- A special connector that attaches the fiber end to the laser source.
- A flexible plastic jacket covers the length of the fiber.

12-Intended use of the device:

This device is indicated for use to perform laser photocoagulation treatments inside the eye (i.e., panretinal photocoagulation, macular treatments, endophotocoagulation to ciliary processes, laser trabeculoplasty), during surgical interventions (e.g.: trans pars plana vitrectomy). The operating wavelength is 514 to 532 nm.

13-Safety and Effectiveness of the device:

This device is safe and effective as the other predicate device cited above.
This is better expressed in the tabulated comparison (Paragraph 14 below)

14-Summary comparing technological characteristics with other predicate device:

Please find below a tabulated comparison supporting that this device is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached.

FDA file reference number	510k 010372
Attachments inside notification submission file	Appendix 1 to 5
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**
Indications for use	Identical
Target population	Identical
Design	Similar
Materials	Similar
Performance	Identical
Sterility	Similar (Ethylene Oxide)
Biocompatibility	Similar
Mechanical safety	Similar
Chemical safety	Similar
Anatomical sites	Identical
Human factors	Identical
Energy used and/or delivered	Identical
Compatibility with environment and other devices	Identical
Where used	Identical
Standards met	Similar
Electrical safety	Identical (not applicable)
Thermal safety	Identical (not applicable)
Radiation safety	Identical (not applicable)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 0 2002

Mr. Jay Mansour
Director, QA/RA
OpthalMed LLC
1308 Morningside Park Drive
Alpharetta, Georgia 30022

Re: K021696
Trade/Device Name: 20G SMA Laser Fiber, Model LF20;
25G SMA Laser Fiber, Model LF25
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: GEX
Dated: May 16, 2002
Received: May 22, 2002

Dear Mr. Mansour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html .

Sincerely yours,

for Mark N. Milkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021696

Device Name: SMA LASER FIBER (20g & 25g)

Indications For Use:

THIS DEVICE IS INDICATED FOR USE TO PERFORM LASER PHOTOCOAGULATION TREATMENTS INSIDE THE EYE (i.e., PANRETINAL PHOTOCOAGULATION, MACULAR TREATMENTS, ENDOPHOTOCOAGULATION TO CILIARY PROCESSES, LASER TRABECUPLASTY), DURING SURGICAL INTERVENTIONS (e.g.: TRANS PARS PLANA VITRECTOMY).
THE OPERATING WAVELENGTH IS 514 TO 532 nm

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)
Division of General, Restorative
and Neurological Devices

Prescription Use ..... OR Over-The-Counter Use
(Per 21 CFR 801.109) 510(k) Number K021696

(Optional Format 1-2-96)

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